

3. Defendant Bachem Americas, Inc. is a California Corporation with its principle place of business at 3132 Kashiwa St., Torrance, CA 90505. Bachem Americas, Inc. may be served through its registered agent, Michael Brenk, 3132 Kashiwa St., Torrance, CA 90505.

4. Defendant Bachem, Inc. is a California Corporation with its principle place of business at 3132 Kashiwa St., Torrance, CA 90505. Bachem, Inc. may be served through its registered agent, Michael Brenk, 3132 Kashiwa St., Torrance, CA 90505.

5. Defendant Peninsula Laboratories, LLC is a California Limited Liability Company with its principle place of business at 3132 Kawisha St., Torrance, CA 90505. Peninsula Laboratories, LLC may be served through its registered agent, Michael Brenk, 3132 Kashiwa St., Torrance, CA 90505.

II. JURISDICTION AND VENUE

6. This is a civil action for damages and injunctive relief for patent infringement under the patent laws of the United States, 35 U.S.C. §101 *et seq.* The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1338 (patents).

7. This Court has personal jurisdiction over Defendants Bachem Bioscience, Inc., Bachem Americas, Inc., Bachem, Inc. and Peninsula Laboratories, LLC (hereinafter, collectively, the “Defendants”) because Defendants have committed acts of infringement within this District, and Defendants operate a website allowing Texas residents to directly purchase infringing products.¹

¹ *Bellorin, et al. v. Bridgestone/Firestone, Inc.*, 236 F.Supp.2d 670 (W.D. Tex. 2001); *Zippo Manuf. Co. v. Zippo Dot Com, Inc.*, 952 F.Supp.1119 (W.D. Pa. 1997).

8. Venue in this District is proper under 28 U.S.C. §1391(b) and 28 U.S.C §1400(b). Defendants are residents of this District under 28 U.S.C. §1391(c).

III. STATEMENT OF FACTS

9. Dr. Siler-Khodr is a world-renown researcher and developer of analogs in the field of gonadotropin releasing hormones (“GnRH”). Dr. Siler-Khodr has dedicated her career as a scientist to the study of GnRH isoforms, and their effects on systems and diseases of the human body, including the reproductive system and associated disorders, the immune system and immunological disorders, and even cancer.

10. Gonadotropin releasing hormone (GnRH) are hormones produced in tissues such as the hypothalamus to stimulate the pituitary secretion of follicle stimulating hormone (“FSH”) and luteinizing hormone (“LH”) in both male and female mammals.

11. In the scientific community, GnRH is also known as Luteinizing Hormone Releasing Hormone, and is commonly abbreviated “LHRH.”

12. Since the mid-1970’s Dr. Siler-Khodr has extensively studied GnRH, and its effects on the human reproductive system. At that time, only one isoform of GnRH, referred to as GnRH I, was known to exist in humans, and it was identified in the pituitary and the hypothalamus.

13. In the 1970’s, Dr. Siler-Khodr discovered the presence of GnRH in the human placenta, and discovered that placental GnRH could stimulate human chorionic gonadotropin (“hCG” – a hormone produced during pregnancy). Dr. Siler-Khodr also discovered that the binding affinity of certain chorionic receptors in the placenta for GnRH was greatly reduced in comparison to the GnRH receptor found in the human

pituitary. Dr. Siler-Khodr's discoveries lead to several publications authored by her in the late 1970's and 1980's.

14. By the 1990's it was discovered that GnRH was also present in mammalian reproductive tissues such as the testes and ovaries. Like the placental receptors, binding affinity of the receptors for the GnRH in these tissues was greatly reduced in comparison to the pituitary GnRH receptors.

15. Prior to the early 1990's, GnRH I was the only form of GnRH known to exist in mammals, including humans. However, in the mid to late 1990's, it was discovered that another isoform of GnRH, commonly known today as "GnRH II" or "Chicken II GnRH", was present in mammalian brains.

16. Throughout the 1990's Dr. Siler-Khodr studied GnRH II, and eventually was able to show that GnRH II was produced by the placenta and binds to a chorionic GnRH receptor with high affinity.

17. However, Dr. Siler-Khodr also discovered in the 1990's that all GnRH isoforms are highly degraded by a substance called a post-proline peptidase, which is present in the human placenta and blood.

18. Therefore, in the mid 1990's Dr. Siler-Khodr turned her efforts to designing an analog of GnRH II that would resist degradation by the post-proline peptidase and would bind with high affinity to placental GnRH receptors.

19. By 1997 or 1998, Dr. Siler-Khodr had developed an analog of GnRH II that she believed would resist degradation by the post-proline peptidase and would bind with high affinity to placental GnRH receptors.

20. Defendants have at all relevant times engaged in the business of offering and providing custom synthesis of amino acid derivatives, peptides, and other immunological substances to scientists in the United States and abroad. Attached hereto as Exhibit A is a true and correct copy of a web page taken from Defendants' website, www.bachem.com, describing Defendants' services.

21. Once Dr. Siler-Khodr had designed her GnRH II analog in the late 1990's, Dr. Siler-Khodr solicited Defendant Peninsula Laboratories, LLC to produce the GnRH II analog exclusively for Dr. Siler-Khodr so that she could test the effectiveness of her GnRH II analog in clinical trials and laboratory experiments. No contract was signed between Dr. Siler-Khodr and Defendant Peninsula Laboratories, LLC. However, Dr. Siler-Khodr filled out an order form and paid Defendant Peninsula Laboratories, LLC to make the GnRH II analog for her.

22. Dr. Siler-Khodr never gave Defendants permission or license to sell her GnRH II analog to any third party.

23. Dr. Siler-Khodr never transferred ownership of her GnRH II analog to Defendants or any other third party.

24. After receiving the GnRH II analog from Defendant Peninsula Laboratories, LLC, Dr. Siler-Khodr performed many tests and experiments. The results of the tests and experiments showed that Dr. Siler-Khodr's analog resisted degradation by post-proline peptidases and endopeptidases, and was capable of binding with high affinity to human chorionic, placental and ovarian GnRH receptors.

25. Dr. Siler-Khodr's work in the late 1990's led to the discovery that her GnRH II analog could be administered to a pregnant mammal, including a pregnant

human, to help maintain pregnancy. Conversely, Dr. Siler-Khodr's GnRH II analog could also be administered to a human (or other mammalian) female in such a dose range and fashion to provide post-coital birth control.

26. On October 15, 1999, Dr. Siler-Khodr filed United States Patent Application No. 09/419,161 in the United States Patent Office. This Patent Application was allowed, and issued on November 27, 2001 as United States Patent No. 6,323,179 (hereinafter the "'179 Patent") for "Chicken GnRH Analogs and Uses Thereof in Regulation of Fertility and Pregnancy." A true and correct copy of the '179 Patent is attached hereto as Exhibit B.

27. The '179 Patent is a valid United States Patent. Dr. Siler-Khodr is the sole inventor and sole owner of the '179 Patent.

28. Claim 1 of the '179 Patent is an independent claim. Claim 1 of the '179 Patent claims:

"A Chicken II GnRH decapeptide analog, having the sequence p-Glu-His-Trp-Ser-His-Xaa1-Trp-Tyr-Pro-Xaa2, capable of binding to human chorionic, placental or ovarian GnRH receptors and active in the presence of a post-proline peptidase or an endopeptidase, said analog comprising a D-amino acid substitution at position 6 and an ethylamide or aza-Gly-amide substitution at position 10."

29. Claim 2 of the '179 Patent is a dependent claim, depending from Claim 1.

Claim 2 of the '179 Patent claims:

"The Chicken II GnRH analog decapeptide analog of claim 1 wherein the Chicken II GnRH analog is further defined as: D-Arg(6)-Chicken II GnRH-ethylamide; or D-Arg(6)-Chicken II GnRH-aza-Gly(10)-amide."

30. Dr. Siler-Khodr recently discovered that Defendants are making, offering for sale, selling and distributing the GnRH II analog covered by Claims 1 and 2 of the '179 Patent within the United States.

31. Attached hereto as Exhibit C is a true and correct copy of a Product Monograph distributed by Defendants to the public. The Product Monograph discloses a line of LHRH products offered for sale by Defendants.

32. At the top of page 5 of Defendants' Product Monograph, Defendants advertise Product No. H-6038, a "(D-Arg⁶, Azagly¹⁰)-LHRH II (human, chicken)" analog, which is also disclosed therein below as (D-Arg⁶, Azagly¹⁰)-GnRH II (human, chicken).

33. Defendants disclose the sequence of Product No. H-6038 (hereinafter the "Infringing Product") on page 5 of Defendants' Product Monograph as Pyr-His-Trp-Ser-His-D-Arg-Trp-Tyr-Pro-Azagly-NH₂.

34. Defendants disclose on page 5 of Defendants' Product Monograph that the Infringing Product is "[u]seful LHRH analog for the site-specific regulation of the ovarian function with a limited effect on pituitary function."

35. Defendants disclose on page 5 of Defendants' Product Monograph a reference "[18]" in connection with the Infringing Product. On page 13 of Defendants' Product Monograph, reference 18 is disclosed to be an article written by Dr. Siler-Khodr in 2003. A true and correct copy of Dr. Siler-Khodr's article is attached hereto as Exhibit D. Therein, Dr. Siler-Khodr discloses one form of her analog, namely, D-Arg(6) GnRH II-aza-Gly(10)-NH₂.

36. Defendants acknowledge in Defendants' Product Monograph that the Infringing Product is Dr. Siler-Khodr's GnRH II analog.

37. Defendants also offer the Infringing Product for sale in the United States through their website, www.bachem.com. Attached hereto as Exhibit E are true and correct copies of screenshots taken from Defendants' website, www.bachem.com, showing Defendants' offer for sale of the Infringing Product.

38. Referring to Exhibit E, from Defendants' homepage, typing the word "Khodr" in Defendants' search box and clicking on "search catalog" leads directly to the Infringing Product. Clicking on the Infringing Product leads to the offer for sale of the Infringing Product in either (a) 1mg, (b) 5mg or (c) "Bulk Quote" quantities. The offer for sale page of Defendants website also attributes the analog as Dr. Siler Khodr's analog.

39. Claim 1 of the '179 Patent claims a GnRH II decapeptide analog having the sequence p-Glu-His-Trp-Ser-His-Xaa1-Trp-Tyr-Pro-Xaa2, where Xaa1 is a D-amino acid and Xaa2 is either an ethylamide or aza-Gly-amide.

40. The Infringing Product is a GnRH II decapeptide analog.

41. The Infringing Product has pyroglutamic acid at the first amino acid position.

42. The Infringing Product has Histidine at the second amino acid position.

43. The Infringing Product has Tryptophan at the third amino acid position.

44. The Infringing Product has Serine at the fourth amino acid position.

45. The Infringing Product has Histidine at the fifth amino acid position.

46. The Infringing Product has D-Arginine at the sixth amino acid position.

D-Arginine is a D-amino acid.

47. The Infringing Product has Tryptophan at the seventh amino acid position.

48. The Infringing Product has Tyrosine at the eighth amino acid position.

49. The Infringing Product has Proline at the ninth amino acid position.

50. The Infringing Product has aza-Gly-amide at the tenth amino acid position. Aza-Gly-amide is one of the possible required substitutions of Claim 1 of the '179 Patent.

51. The Infringing Product is capable of binding to human chorionic, placental or ovarian GnRH receptors.

52. The Infringing Product is active in the presence of a post-proline peptidase or endopeptidase.

53. Claim 2 of the '179 Patent claims a GnRH II decapeptide analog of claim 1 further defined as either D-Arg(6)-GnRH II-ethylamide, or D-Arg(6)-GnRH II-aza-Gly(10)-amide.

54. The Infringing Product is a GnRH II decapeptide analog.

55. The Infringing Product is D-Arg(6)-GnRH II-aza-Gly(10)-amide.

56. The Infringing Product infringes Claims 1 and 2 of the '179 Patent.

57. Defendant Bachem Americas, Inc. is a sales and distribution center for active pharmaceutical ingredients and research grade products.

58. On information and belief, Bachem Americas, Inc. has sold, offered for sale and/or distributed the Infringing Product within the United States.

59. Defendant Bachem Bioscience, Inc. is a "logistics and distribution" center for the American continents.

60. On information and belief, Bachem Bioscience, Inc. has sold, offered for sale and/or distributed the Infringing Product within the United States.

61. Defendant Bachem, Inc. is a development and manufacturing center for active pharmaceutical ingredients, peptides, complex organic molecules, and research grade products.

62. On information and belief, Bachem, Inc. has made, manufactured, sold, offered for sale and/or distributed the Infringing Product within the United States.

63. Defendant Peninsula Laboratories, LLC is a development and manufacturing center for immunology products, antibodies, EIA/ELISA and RIA kits, custom immunoassay kits, and peptide and protein labeling products. On information and belief, Bachem, Inc. acquired Peninsula Laboratories, LLC in 1999.

64. On information and belief, Peninsula Laboratories, LLC has made, manufactured, sold, offered for sale and/or distributed the Infringing Product within the United States.

65. On information and belief, Defendants have made, manufactured, sold, offered for sale and distributed the Infringing Product since as least as early as 2006.

IV. COUNT I **PATENT INFRINGEMENT**

66. Dr. Siler-Khodr repeats and re-alleges the allegations contained in the foregoing paragraphs.

67. Defendants' acts of making, manufacturing, selling, offering for sale and/or distributing the Infringing Product as described herein constitutes infringement of

the '179 Patent and/or induces infringement of the '179 Patent pursuant to 35 U.S.C. §271.

68. Defendants' acts of infringement complained of herein are deliberate and willful, and will continue unless enjoined by this Court.

69. As a result of Defendants' acts of infringement, Dr. Siler-Khodr has been damaged, and will continue to be damaged if not enjoined by this Court.

70. Defendant's willful and deliberate acts of infringement make this case exceptional under 35 U.S.C. §285, and such damages should be increased to the maximum amount allowable by law, including an award of attorney's fees to Dr. Siler-Khodr.

V. COUNT II
FEDERAL UNFAIR COMPETITION

71. Dr. Siler-Khodr repeats and re-alleges the allegations contained in the foregoing paragraphs.

72. By the acts complained of hereinabove, Defendants have unfairly competed with Dr. Siler-Khodr. Specifically, by selling and offering for sale Dr. Siler-Khodr's GnRH II analog as their own, without her permission or license, Defendants have created a false designation of origin, false or misleading description of fact, or false or misleading misrepresentation of fact which is likely to cause confusion, or to cause mistake, or to deceive as to (a) the affiliation, connection, or association of Defendants with Dr. Siler-Khodr, or (b) as to the origin, sponsorship, or approval of Defendants' goods, services, or commercial activities by Defendants.

73. The activities complained of hereinabove constitute unfair competition under Section 43 of the Lanham Act, 15 U.S.C. §1125, that is damaging Dr. Siler-Khodr, and will continue to damage Dr. Siler-Khodr unless enjoined by this Court.

**VI. COUNT III
CIVIL CONSPIRACY**

74. Dr. Siler-Khodr repeats and re-alleges the allegations contained in the foregoing paragraphs.

75. By the acts of Defendants complained of hereinabove, Defendants have, with each other and others, formed a combination to accomplish an unlawful purpose, or a lawful purpose by unlawful means. Defendants had a meeting of the minds on the object or course of action, and have committed unlawful, overt acts to accomplish the object or course of action. Dr. Siler-Khodr has suffered injury as a result of the wrongful acts of Defendants.

76. Defendants have conspired and acted in concert with one another to accomplish the objective of selling Dr. Siler-Khodr's GnRH II analog without permission or license to do so. Defendants have misappropriated and used Dr. Siler-Khodr's property without permission to accomplish this objective to the detriment of Dr. Siler-Khodr.

VII. DEMAND FOR JURY TRIAL

Plaintiff, Dr. Siler-Khodr hereby demands a trial by jury.

PRAYER

WHEREFORE, Plaintiff, Theresa M. Siler-Khodr, respectfully prays that this Court enter judgment against Defendants as follows:

- A. Finding that Defendants have infringed Plaintiff's U.S. Letter Patent No. 6,323,179;
- B. Finding that Defendants have committed civil conspiracy against Plaintiff;
- C. Finding that Defendants have unfairly competed with Plaintiff in violation of the Section 43 of the Lanham act, 15 U.S.C. §1125;
- D. That Plaintiff be awarded damages against Defendants, jointly and severally, as a result of the acts complained of herein;
- E. That Defendants' acts be determined to be willful, and as a result, damages be increased to the maximum amount allowed by law;
- F. That this case be found to be exceptional, and that Plaintiff be awarded her attorneys' fees and costs;
- G. That Plaintiff be awarded prejudgment and post-judgment interest;
- H. That Defendants, their respective officers, agents, servants, employees, attorneys, and all of the persons in active concert of participation with Defendants during the pendency of this action and permanently thereafter be enjoined as follows:
 - 1. From any and all acts in infringement of the '179 patent;
 - 2. From any and all acts of unfair competition;
 - 3. Requiring an accounting for profits received by Defendants as a result of the acts complained of herein;

4. Directing that all items infringing the '179 patent be delivered to Plaintiff for destruction; and

I. For such other and further relief to which Plaintiff shows herself to be justly entitled.

Respectfully Submitted,

/Robert L. McRae/
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